zation of health services. The overall C/B ratio turned out to be 1:6.52, in other words, compared to control group, asthma education programs reduce direct medical costs by $6.52 for each dollar spent in providing the education.
CONCLUSION: Our study shows that the asthma education programs are beneficial in reducing the direct medical costs associated with asthma. These findings suggest that education programs benefit the patient and lead to their well being which in turn will benefit both the patient and the third-party payers.

PRD5

THE FIRST PHARMACOECONOMIC STUDY IN ASTHMA: SOME IMPORTANT OBSERVATIONS

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Treatment options for control of asthma are numerous. However, as for other diseases, there are often differences between clinical trials and what takes place in clinical practice.
OBJECTIVES: To present some methodological issues in relation to the first "real-life" pharmacoeconomics study (PECT) in asthma, comparing the cost-effectiveness of budesonide Turbuhaler versus sodium cromoglycate Spinhaler for moderately asthmatic children, aged 5–11 years.
METHODS: One hundred thirty-eight Swedish patients were randomized to one of the two treatments. Patients were then treated according to local clinical practice on an open basis for 12 months. Thus, any additional therapy was allowed, including switching to the comparator. The objective was to reach the same degree of patient asthma control in both groups. There were six scheduled study visits. Efficacy (asthma control) and resource use were recorded in patient diaries and case report forms.
RESULTS: 1) A number of problems in relation to randomization, such as center effects and sample selection bias, were experienced. 2) A dilution of difference in effect was experienced due to the fact that 36% of patients on sodium cromoglycate had to switch to budesonide because of poor control of asthma (as judged by the physician). 3) Because there was insufficient data available on which to base a power calculation, too few patients were recruited. 4) Due to large standard deviations and the problems listed above, a significant advantage in budesonide costs could only be identified when various background factors were taken into account in a multiple regression analysis.
CONCLUSIONS: A number of different methodological problems compared to ordinary piggy-back economic evaluations arise in PECTs. Careful consideration of design is necessary to ensure high-quality research. Innovative methodological approaches, such as multiple regression analysis, are required.

PRD7

THE USE OF GENERALIZED ESTIMATING EQUATIONS IN LONGITUDINAL STUDIES OF RESOURCE UTILIZATION: THE CASE OF ASTHMA

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OBJECTIVE: To evaluate the importance of accounting for correlations between observations when analyzing repeated measures of healthcare utilization.
METHODS: Poisson regression was applied with and without generalized estimating equations to analyze β-agonist use, healthcare contacts, and nocturnal awakenings in chronic asthmatics in two large similarly designed, 12-week, randomized trials of Montelukast, a once daily leukotriene receptor antagonist, compared to placebo. Data on β-agonist use and nocturnal awakenings were recorded on daily diary cards. Healthcare contacts included visits to physicians, the emergency room, and hospitalizations documented as not mandated by the protocols.
RESULTS: Montelukast compared to placebo decreased the rate of days of β-agonist use by 9.6% ($p < 0.0001$), nights with awakenings by 22.5% ($p < 0.0001$) and healthcare contacts by 23.0% ($p = 0.09$) when analyzed without generalized estimating equations. Use of generalized estimating equations did not change the parameter estimates for any of the health outcomes measured, but did increase the standard errors and confidence intervals in all cases. The increase in the standard errors ranged from 19.1% to 355.1%. β-agonist use and nights with awakenings remained statistically significant. However, healthcare contacts became less significant ($p = 0.16$).
CONCLUSION: Failure to account for correlations between observations may lead to erroneous conclusions based on significance levels that are too small. In large samples, exceeding 100–200 patients, generalized estimating equations provide one method of obtaining correct significance levels and confidence intervals when data are correlated. The example above included daily values for 12 weeks in 1300 patients. Other methods of adjusting for correlated data are needed in smaller samples.

PRD8

A RETROSPECTIVE DATABASE STUDY OF PATIENT ADHERENCE WITH ASTHMA TREATMENT REGIMENS

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OBJECTIVES: Healthcare providers need accurate information about all aspects of healthcare delivery. Clinical trials provide useful information concerning the clinical efficacy of treatment, but they are not representative of the routine conditions with which patients must contend when following treatment regimens. Database studies are being used increasingly to provide information about patient adherence under routine conditions.